



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rothschild *et al.*

Serial No: 10/719,523

Art Unit: 1636

Filing Date: 11/21/2003

Examiner: Schlapkohl, W.

Title: **Methods for the Detection, Analysis and Isolation of Nascent Proteins**

**RESPONSE TO RESTRICTION REQUIREMENT  
MAILED JANUARY 25, 2006**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 2/27/2006

By: 

Traci E. Light

Dear Sir or Madam:

Please enter the following on the record in response to the above cited Restriction Requirement mailed on January 25, 2006.

**REMARKS**

The Examiner has stated that the application, as filed, is subject to a restriction requirement and requires an election of one of fifty-two (52) claim groupings. The Examiner has divided the claims into: i) Groups I-XXV consisting of Claims 2-8 and 10-15 (Class 536, Subclass 24.33); ii) Groups XXVI-L consisting of Claims 17-23 (Class 435, Subclass 91.2); and iii) Groups LI & LII consisting of Claims 24-30 and Claims 31-37 (Class 435, Subclass 69.1). The Examiner has assigned different Group numbers to each possible permutation of the claimed sequences and/or genes to create the extraordinary number of Groups identified within the Restriction Requirement. *See Restriction Requirement pp 2 – 10.* The Applicants request reconsideration for rejoinder of: i) Groups I-XXV to form a New Group I; ii) Groups XXVI-L to form a New Group II; and iii) Groups LI & LII for form a New Group III. The Applicants hereby traverse the presently pending Restriction Requirement.

The Applicants disagree not only with the Group assignments but also the Examiner's improper procedure in not including the Applicants independent claims (i.e., Claim 1, 9 & 16) in any of the identified groups. Restriction practice requires the withdrawal of non-elected groups after an election is placed on the record. The Examiner has placed only dependent claims on the record for consideration.

**I. There Is No Undue Search Burden**

The Examiner attempts to justify this extensive Restriction Requirement by complaining that:

... this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases ... resulting in a corresponding increase in computer search time and examination time ... therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

*Restriction Requirement, pg. 12.* The Examiner's highly conclusory statements do not stand up to close examination.

**A. MPEP § 803 ¶ 5 Has Not Been Satisfied**

The Applicants argue that the Examiner's unsupported reasons for an "undue burden" do not meet statutory standards:

... a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search ...

*MPEP § 803 ¶ 5.* The Examiner has created: i) twenty-five Groups within Class 536, Subclass 24.33); ii) twenty-five Groups within Class 435, Subclass 91.2; and iii) two Groups within Class 435, Subclass 69.1. Each of these three Groups respectively encompass the same classification. This is contrary to the MPEP requirement that an undue burden requires Groups having separate classifications. Further, the Examiner has not shown that the elements have "separate status in the art" or involve a "different field of search".

**B. More Than One Sequence Is Not An Undue Burden**

The Examiner is refusing to search Claim 7 (and other identical claims) which reads in part "... wherein second epitope is selected from the group consisting of SEQ ID NOS: 5, 6, 7, 8 and 9" and Claim 8 (and other identical claims) which reads in part "... wherein said template comprises a region of a gene, said gene selected from the group consisting of the APC gene, the NF1 gene, the NF2 gene, the BRCA1 gene and the BRCA2 gene. Claim 7 presents only five (5) sequences and Claim 8, in reality, only presents three (3) different gene classes.

The Applicants' Markush group member composition comports with the standard MPEP guidelines associated with evaluating a Restriction Requirement:

The members of the Markush group ... ordinarily must belong to a recognized physical or chemical **class** or to an art-recognized **class**.

*MPEP 803.02: Markush Claims* [emphasis added]. In Claims 7 & 8 (and other identical claims), SEQ ID NOS: 5, 6, 7, 8 and 9, and the APC/NF1/NF2/BRCA1/BRCA2 genes meet the "physical/chemical/art-recognized class" requirement. Nucleotide sequences are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class. Further, the genes of Claim 8 are all art-recognized cancer-causing genes. The Examiner is improperly attempting to redefine scientific dogma by arguing that nucleic acids of different sequences belong to a different physical and/or chemical class. Such an assertion is scientifically unfounded.

Further, the Applicant's Markush group member number comports with the standard guidelines for not requiring a Restriction Requirement:

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions ...

*MPEP 803.02: Markush Claims* [emphasis added]. The Applicants argue that the five (5) members of Claim 7 (and other identical claims) and the five (5) members of Claim 8 meet the intent of "sufficiently few in number" such that the Examiner is not faced with any undue burden. Further, as described above, these Markush elements meet the "closely related" requirement because they are all either nucleic acids (i.e., for example, Claim 7) or cancer causing genes (i.e., for example, Claim 8). The Applicants' point to the underscored sentence above to reiterate that it is not relevant if the Examiner continues to believe that independent and distinct inventions are still present, the pending Restriction Requirement is, by law, unreasonable and must be withdrawn.

**C. Increased Database Size Is Not An Undue Burden**

The Examiner attempts to argue that because more and more sequences are being deposited in centralized databases that this creates an undue burden in searching these databases. Such a supposition is preposterous since these electronic databases are known to return results within seconds-to-minutes, not hours as the Examiner seems to infer. There is no evidence on

the record showing that the Examiner's computer is sufficiently slow to create any undue search burden.

**D. The Examiner Has Improperly Asserted New USPTO Policy**

The Examiner unequivocally states that "...the Office no longer permit[s] examination of more than one sequence..." (*supra*). The Applicant's challenge the Examiner to provide any authorized USPTO rule or regulation attesting to this statement. Otherwise, the Examiner is not permitted to rely on such a conclusion. The Examiner is reminded that PTO decisions are reviewed using the standard set forth in the *Administrative Procedure Act*, 5 U.S.C. § 706. *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). Under that statute, actions are set aside that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Moreover, factual findings are set aside that are unsupported by substantial evidence. *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002).

**II. Default Election**

The Applicants provide an election of the Examiners' offered groups only because required to do so under 35 U.S.C. § 121. The Applicants, with traverse, elect Group I.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

Dated: Feb 27, 2006

By: Thomas C. Howerton  
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